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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/147,443      | 01/21/1999  | ANDREAS MORELL       | P63221US0           | 1730             |

7590

09/23/2003

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| EXAMINER |
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VANDERVEGT, FRANCOIS P

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1644

DATE MAILED: 09/23/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

4

# Office Action Summary

Application No.

09/147,443

Applicant(s)

MORELL ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 22-44 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/147,443.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1644

### DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a CPA of U.S. Application Serial Number 09/147,443, which is a rule 371 continuation of PCT Serial Number PCT/EP97/03253.

Claims 1-21 have been canceled previously.

Claims 22-44 have been added and are currently pending.

### *Continued Prosecution Application*

The request filed on June 11, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/147,443 is acceptable and a CPA has been established. An action on the CPA follows.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 22-32, drawn to a Rhesus D antigen-specific antibody with a heavy chain sequence defined by SEQ ID NO: 58 or a functional variant thereof, classified in class 530, subclass 387.5.
- II. Claims 33-43, drawn to a Rhesus D antigen-specific antibody with a light chain sequence defined by SEQ ID NO: 60 or a functional variant thereof, classified in class 530, subclass 350.
- III. Claim 44, drawn to a method of treating a hematologic disorder in a subject, classified in class 424, subclass 137.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions specify the identity of the heavy chain of an immunoglobulin molecule in Group I and the light chain of an immunoglobulin molecule in Group II. The two groups specify different polypeptides which can be combined but are not necessarily so, being able to be combined with other partners.

Art Unit: 1644

Inventions I & II and III are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the immunoglobulin molecules as set forth in Groups I & II do not need to include the other as part of the binding agent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

In Group I, Applicant must choose from a specific VH sequence selected from SEQ ID NO: 58 or the functional variants defined by SEQ ID NOs: 2, 6, 10, 14, 18, 22, 26, 30, 34, 38, 42, 46, 50, 54, and 62.

Additionally, Applicant must choose a specific VL sequence selected from SEQ ID NO: 60 or the functional variants defined by SEQ ID NOs: 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, and 64.

In Group II, Applicant must choose from a specific VL sequence selected from SEQ ID NO: 60 or the functional variants defined by SEQ ID NOs: 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, and 64.

Additionally, Applicant must choose a specific VH sequence selected from SEQ ID NO: 58 or the functional variants defined by SEQ ID NOs: 2, 6, 10, 14, 18, 22, 26, 30, 34, 38, 42, 46, 50, 54, and 62.

In Group III, Applicant must choose from a specific VL sequence selected from SEQ ID NO: 60 or the functional variants defined by SEQ ID NOs: 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, and 64.

Additionally, Applicant must choose a specific VH sequence selected from SEQ ID NO: 58 or the functional variants defined by SEQ ID NOs: 2, 6, 10, 14, 18, 22, 26, 30, 34, 38, 42, 46, 50, 54, and 62.

Additionally, Applicant must select a species of disorder from haemolytic disease of the newborn, immune thrombocytopenic purpura and mistransfusion of Rhesus incompatible blood.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 22, 33, and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any

Art Unit: 1644

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D. *R*  
Patent Examiner  
September 22, 2003

*Phillip Gambel*  
PHILLIP GAMBEL, PH.D.  
PRIMARY EXAMINER  
*Tech Center 600*  
*9/24/03*